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REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60
(Small Entity)

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION	ART UNIT
P1113DIV	CLASS 623	SUBCLASS	08/681,230	3308

Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231

This is a request for filing a ☐ continuation ☒ divisional application under 37 CFR 1.60 of pending prior application,
Serial Number 08/681,230 filed on July 22, 1996 and entitled:
Human Spinal Disc Prosthesis

1. Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the attached papers are a true copy of the latest signed prior application, Serial Number 08/681,230, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like are made punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	9	- 20 =	0	x \$11.00	\$0.00
Indep. Claims	4	- 3 =	1	x \$40.00	\$40.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$385.00
TOTAL FILING FEE					\$425.00

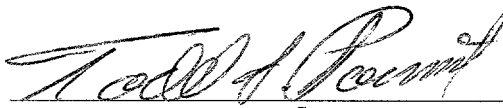
2. ☒ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27
☐ is enclosed.
☒ was filed in prior application Serial Number 08/681,230 and such status is still proper and desired (37 CFR 1.28(a)).
3. ☒ The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 07-0181. A duplicate copy of this sheet is enclosed.
4. ☒ A check in the amount of \$425.00 is enclosed.
5. ☒ Cancel in this application original claims 1-22, 31-34, and 36-53 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
6. ☐ Amend the specification by inserting before the first line the sentence: "This application is a ☐ continuation ☐ division of application Serial Number _____ filed _____ which application is now:
☐ abandoned.
☐ pending.
☐ other (explain):
7. ☐ Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized by 37 CFR 1.138 and before payment of issue fee.)

REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60
(Small Entity)

8. ☒ New formal drawings are enclosed.
9. ☐ Priority of foreign application number _____ filed on _____ in _____
_____ is claimed under 35 U.S.C. 119.
Country
- ☐ The certified copy has been filed in prior application Serial Number _____ filed on _____
10. ☒ A preliminary amendment is enclosed.
11. ☒ The prior application is assigned of record to:
Spinal Dynamics Corporation
15400 S.E. 30th Place
Suite 203
Bellevue, WA 98007
12. ☒ Also enclosed:
Express Mail Certificate; Return Postcard
13. ☒ The power of attorney in the prior application is to:
Todd S. Parkhurst
GARDNER, CARTON & DOUGLAS
321 North Clark Street, Suite 3400
Chicago, IL 60610
- a. ☐ The power of attorney appears in the original papers in the prior application.
- b. ☒ Since the power of attorney does not appear in the original papers, a copy of the power of attorney in the prior application is enclosed.
- c. ☒ Address all future correspondence to. (May only be completed by applicant, or attorney or agent of record.)
Todd S. Parkhurst
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321 North Clark Street, Suite 3400
Chicago, IL 60610

Dated:

15 May 1997


Signature

Todd S. Parkhurst

Typed or printed name

26,494

Registration Number (if applicable)

- ☐ Inventor(s)
- ☐ Assignee of complete interest
- ☒ Attorney or agent of record
- ☐ Filed under 37 C.F.R. 1.34(a)

cc:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
 Bryan et al.)
) Examiner:
 Serial No.: Not yet assigned)
) Group Art Unit:
 Filed: Concurrently herewith)
)
 For: Human Spinal Disc Prosthesis)

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Please amend the above-identified application as follows:

On page 1, please delete the sentence after the title and insert the following:

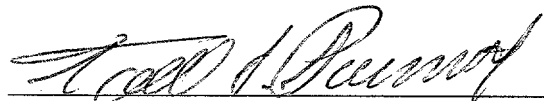
--This is a divisional of U.S. Patent Application Serial No. 08/681,230, filed July 22, 1996, which is pending and which is a continuation-in-part of U.S. Patent Application Serial No. 08/339,490, filed November 14, 1994, which is abandoned.--

REMARKS

The purpose of the above amendment is to identify the continuing information for the instant application. Notice of allowance for this application is earnestly awaited.

Respectfully submitted,

Date: 15 May 1997



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**EXPRESS MAILING CERTIFICATE
UNDER 37 CFR § 1.10**

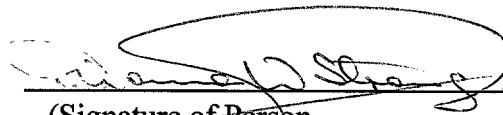


EM549228239US
"Express Mail" Mailing Number

May 15, 1997
Date of Deposit

I hereby certify that a Request for Filing a Patent Application under 37 CFR 1.60; a Preliminary Amendment; a copy of the signed Declaration and Power of Attorney for Docket No. P1113USA; a Specification (19 pages); Drawings (5 pages); a check for \$425.00; and a return post card are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above, addressed to the Assistant Commissioner for Patents; Box: Patent Application; Washington, D.C. 20231.

Diana W. Strong
(Typed or Printed Name of
Person Mailing Application)


(Signature of Person
Mailing Application)

(P1113DIV)

HUMAN SPINAL DISC PROSTHESIS

This is a continuation-in-part of U.S. Patent Application Serial No. 08/339,490, filed November 14, 1994, which is pending.

Background of the Invention

This invention relates generally to human prostheses, and especially to spinal column vertebral disc prostheses. The invention also relates to surgical procedures for preparing the patient to receive a vertebral disc endoprosthesis, and for implanting that endoprosthesis in the patient's spine.

The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy -- as the name implies -- involves the simple removal of the disc without attempt to replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and

related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R.A.: The Results of Anterior Interbody Fusion of the Cervical Spine, J. Bone Joint Surg., 440A: 1569-1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

Spine surgery occasionally involves fusion of the spine segments. In addition to the problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic rods, hooks, plates and screws being appended to the patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Patent 5,031,437, describes a spinal disc prosthesis having upper and lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S. Patents 4,917,704 and 4,955,908, disclose intervertebral prostheses, but the prostheses are described as solid bodies.

U.S. Patents 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

It is the primary aim of the present invention to provide a vertebral disc endoprosthesis which will perform effectively and efficiently within a patient's spine over a long period of time, and which will not encourage degeneration of or cause damage to adjacent natural disc parts.

It is another object to provide a vertebral disc endoprosthesis which does not require pins or other common mechanical hinge elements, yet which permits natural motion of the prosthetic parts and the adjacent natural anatomy.

It is a related objective to provide a new vertebral disc endoprosthesis surgical procedure which will decrease post-operative recovery time and inhibit post-operative disc, vertebral body and spinal joint degeneration.

It is yet another object to provide a method of installing the endoprosthesis so as to accurately mate the endoprosthesis with an adjacent specifically formed bone surface. An associated object is to provide an endoprosthesis which will encourage bone attachment to, and growth upon, adjacent outer surfaces of the endoprosthesis.

Yet another object is to provide a vertebral endoprosthesis in which the parts are non-oncogenic.

Still another object is to provide a vertebral disc endoprosthesis having a resilient element to accommodate shocks and other forces applied to the spine.

Another object is to provide a highly effective vertebral endoprosthesis which includes several disc endoprostheses and one or more prosthetic vertebral bodies. A related object is to provide these elements in a pre-assembled array for implantation in a patient.

Summary of the Invention

To accomplish these objects, the invention comprises a resilient body formed of a material varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion. A concaval-convex means at least partly surrounds that resilient body so as to retain the

resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprostheses can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

To implant this endoprosthesis assembly, information is obtained regarding the size, shape, and nature of a patient's damaged natural spinal discs. If one or more of the patient's vertebral bodies also require replacement, information about those bodies is also obtained. Thereafter, one or more prosthetic disc units and interposed prosthetic vertebral body units are constructed and preassembled in conformity with that information. Finally, the completed and conformed prosthetic disc and vertebral body assembly is implanted in the patient's spine.

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

Brief Description of the Drawings

Fig. 1 is a fragmentary vertical view of a portion of a human spine in which is installed a novel vertebral disc endoprosthesis embodying the present invention;

Fig. 2 is a fragmentary side elevational view similar to Fig. 1 showing the elements of a patient's spine and having a novel vertebral disc endoprosthesis embodying the present invention installed therein;

Fig. 3 is a sectional view taken substantially in the plane of line 3-3 in Fig. 1;

Fig. 4 is an exploded view of the novel vertebral disc endoprosthesis;

Fig. 5 is a vertical fragmentary view of a patient's spine similar to Fig. 1, but showing a series of novel disc endoprosthesis units installed in the spine and interconnected to one another;

Fig. 6 is a fragmentary sectional view of a patient's spine similar to Fig. 3 and taken along line 6-6 in Fig. 5, but showing a natural upper vertebral body, and upper endoprosthetic disc; an adjacent endoprosthetic vertebral body; a second or lower endoprosthetic disc; and a second or lower natural vertebral body;

Fig. 7 is a sectional view taken substantially in the plane of line 7-7 of Fig. 6;

Fig. 8 is a fragmentary side elevational view of the assembly shown in Fig. 6; and

Fig. 9 is a fragment vertical view, similar to Fig. 1, of a portion of a human spine in which is installed a variant form of the novel vertebral disc endoprosthesis the variant form having a prosthetic longitudinal ligament;

Fig. 10 is a sectional view taken substantially in the plane of line 10-10 in Fig. 9;

Fig. 11 is a top view of a retainer means for use with a vertebral disc endoprosthesis;

Fig. 12 is a sectional view taken substantially in the plane of line 12-12 of Fig. 11;

Fig. 13 is a side view of a vertebral disc endoprosthesis having a groove for receiving the retainer means; and

Fig. 14 is a cross-sectional view of the retainer means in use.

Detailed Description

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

Turning more specifically to Figs. 1-3, a portion of a human spine 10 is shown. The illustrated spine 10 has been subjected to a discectomy surgical process. To discourage degeneration of or damage to the natural vertebral bodies 12 and 14 and their respective facet joints, in accordance with the invention, a vertebral disc endoprosthesis 18 is affixed between the adjacent natural vertebral bodies 12 and 14. Here this vertebral disc endoprosthesis 18 comprises a resilient disc body 20 having a relatively stiff annular gasket exterior portion 22 and a relatively supple nuclear central portion 24. The annular gasket 22 can be formed from a suitable biocompatible elastomer of approximately 90 durometer hardness and the nuclear central portion 24 can be formed from a softer biocompatible elastomeric polymer of approximately 30 durometer hardness.

Concaval-convex means 30 surround the resilient body 20 to retain the resilient body 20 between the adjacent natural vertebral bodies 12, 14 in a patient's spine 10. To this end, as shown in Fig. 3, the concaval-convex means 30 comprise two generally L-shaped supports 32 and 34. The supports 32, 34 each have confronting first concaval-convex legs 42, 44, each leg being of relatively constant cross-sectional thickness. Each leg 42, 44 has an outer convex surface 52, 54 for engaging the adjacent bone of the natural vertebral bodies 12, 14.

Corresponding inner concave surfaces 62, 64 in confronting array retain the resilient body 20 in its illustrated compressive force shock-absorbing position. These supports 32 and 34 can undergo principle movement away from one another, but only limited secondary translational, rotational and distractional motion will occur. Each support 32, 34 has a second wing or leg 72, 74 extending generally perpendicularly to the first legs 42, 44 respectively, and adapted for affixation to the adjacent bone structure. To carry out aspects of the invention described below, this affixation is effectively accomplished by cannulated screw devices 82, 84 which may be of a biodegradable type manufactured by Zimmer of Largo, Florida. Each device 82, 84 comprises a screw 92, 94; and a screw anchor 102, 104 adapted to threadably receive the screw extends radially into and seats within the bone structure 12, 14 as especially shown in Fig. 3.

To discourage and prohibit migration of fluids between the endoprosthesis 18 and adjacent parts of the anatomy, a seal member 110 is attached to the supports 32, 34 so as to surround the resilient body 20 comprised of the gasket 22 and nucleus 24, in accordance with another aspect of the invention. Here, this seal member 110 comprises a flexible sheet material having a multiplicity of pores. Preferably, the pores are from about 5 microns to about 60 microns in size. A flexible, strong polymer sheet material from which this seal is formed can be a Kevlar-like material, or it can be Goretex-like material, or other appropriate biocompatible material, such as polyether, polyurethane, or polycarbonate urethane membranes, can be used. Kevlar material is offered by the E. I. DuPont de Nemours Company of Wilmington, Delaware and Goretex material is offered by the W. T. Gore Company of Flagstaff and Phoenix, Arizona. Known sealing material can be applied to the flexible sheet material so as to render the flexible

sheet material substantially impervious to the passage of any fluid. A watertight seal is perfected when the seal 110 is glued or otherwise affixed to the legs 42, 44 and mediate portions of the legs 72, 74 as suggested in Figs. 1-3.

In an alternative embodiment, the watertight seal between the endoprosthesis 18 and adjacent parts of the anatomy can be provided by developing a groove 402 completely encircling the periphery of each of the legs 42, 44. Only one of the grooves is shown in Fig. 13. In this embodiment, the seal member 410 is provided with a beaded edge 412 for each groove. Additionally, a retaining band 415 is provided for each groove to retain the seal member 410 in grooves 402. The retaining bands 415 can be in the form of a biocompatible monofilament wire of, for example, stainless steel or titanium, a synthetic polymer cable or a braided wire cable. As shown in Fig. 11, each retaining band is crimped anteriorly by a crimping sleeve 420. Of course, more than one crimping sleeve may be used, if necessary. Although one sealing arrangement consisting of the groove, beaded edge and retaining band is shown in Fig. 14, it should be understood that the sealing arrangement on the concaval-convex leg of the other support is identical in design and function.

In use, the seal member 410 is placed about the concaval-convex means 30. The retaining bands 415 are then placed adjacent to the respective groove 402 and crimped anteriorly, thereby fitting the bands into the grooves. Each beaded edge 412 prevents the slipping of the seal member underneath the retaining band. Thus, the retaining band, the groove and the beaded edge all cooperate to provide a water-tight seal to prevent the migration of fluids between the endoprosthesis 18 and adjacent parts of the anatomy. Glue can also be used to affix the seal member to the concaval-convex means 30 as a supplemental means for perfecting the seal.

In accordance with another aspect of the invention, the supports 32, 34 are formed of a biocompatible metal which may contain chromium cobalt or titanium. Surface roughening or titanium beading 112, 114 on the exterior surfaces 52, 54 of legs 42, 44 encourages positive bonding between the adjacent bone and the convex surfaces 52, 54.

As suggested in Figs. 9 and 10, a prosthetic longitudinal ligament 250 can be connected between the screws 92, 94 to limit motions between elements of the spine 10 in the area where the endoprosthesis 18 is implanted. This strap 250 may be made of the Kevlar-like material or the Goretex-like material described above, or it may be made of any other strong biocompatible material.

In accordance with another aspect of the invention, multiple endoprosthetic disc units can be placed in series with a straddling interlock appendage providing stability and fixation as shown in Fig. 5. Entire portions of a patient's spine can be replaced by a series of interconnected endoprosthetic vertebral bodies and endoprosthetic disc units. Figs. 6-8 show an upper natural vertebral body unit 312 to which an upper endoprosthetic body 308 has been attached. A lower natural vertebral body 314 has attached, at its upper end, an endoprosthetic disc unit 318. Between these endoprosthetic disc units 308 and 318 is an endoprosthetic vertebral body 320. As suggested by Fig. 7, the endoprosthetic vertebral body 320 need not be irregularly shaped in cross sectional aspect; rather, manufacturing processes may suggest that it have a circular cross-sectional shape. As shown in Figs. 6 and 8, this endoprosthetic vertebral body 320 comprises a titanium element 321, to which are attached the preformed upper and lower endoprosthetic vertebral body upper and lower concaval-convex elements 322, 324. Each concaval-convex element 322, 324 is attached to the prosthetic vertebral body 320, as shown in Fig. 7, by extending set screws 330 through the titanium vertebral body 321 into a stem-like projection 331 extending from each of the concaval-convex elements 322, 324. A hole 360 in the body 320 accommodates the stem-like projections 331 of the concaval-convex elements 322 and 324. The stem-like projection 331 of the concaval-convex elements 322 and 324 is used only in conjunction with a prosthetic vertebral body implant construction 320.

An ear 340 is affixed, as by weldments 341, to a leg 342 extending from a concaval-convex element 322 as illustrated in Figs. 6 and 8. An anchor 352 can be threaded into the endoprosthetic vertebral body 320, and a screw 362 can be turned into the anchor 352 so as to rigidly assemble the leg 342 to a leg 354 extending from the lower endoprosthetic disc unit 318.

The upper disc endoprosthesis 308, the endoprosthetic vertebral body 320, and the lower disc endoprosthesis 318 can all be assembled and interconnected as a unit before implantation in a patient's body when indicated.

As also suggested in Fig. 6, the annular corners 372, 374 of natural vertebral bodies 312, 314 each can extend irregularly radially outwardly of the adjacent disc endoprosthesis 308, 318. However, the corners 382B, 384B of the prosthetic vertebral body 320 do not generally extend significantly outside those disc units 308, 318, thus discouraging vertebral body engagement with and consequent abrasion or other damage to adjacent portions of the patient's natural anatomy. Preferably the endoprosthetic vertebral body 320 is not exactly right cylindrical in shape, but is rather slightly biconical; that is, the endoprosthetic vertebral body 320 has a waist 390 of minimum radius R at an axial medial point as suggested in Fig. 6.

According to yet another aspect of the invention, novel surgical procedures permit effective and permanent installation of the endoprosthetic vertebral body 320 and associated parts. First, a surgeon or medical technician develops information about the size, shape and nature of a patient's damaged vertebral body or bodies from radiographs, CT and/or MRI scans, noting specifically the anterior-posterior and lateral dimensions of the end plate of each involved vertebral body and the vertical height of the anterior aspect of each involved vertebral and/or proximate vertebral body and vertical height of the mid portion of involved and proximate relatively normal intervertebral disc spaces. This information is transmitted by telephone, computer datalink or documentary transport to a specialized laboratory. That laboratory constructs one or more prosthetic assemblies of the sort shown in Fig. 6 in conformity with the received information and this disclosure. Each of the assemblies can include a prosthetic vertebral body 321, and at each body end is a prosthetic disc 308, 318. Each prosthetic disc unit comprises, in turn, the concaval-convex elements 30; the resilient body 20 interposed between the concaval-convex elements; and the seal unit 110 secured around the interior legs and resilient body. Thereafter, the completed and conformed assembly is implanted in the patient's spine 10.

When the unit or units have been received and the patient properly prepared, the damaged natural spinal disc or discs and vertebral body or bodies are removed and the adjacent spinal bone surfaces are milled or otherwise formed to provide concave surfaces to receive the confronting convex surfaces 52, 54. Thereafter, the disc units and vertebral body are installed in the patient's spine.

To accurately locate the concaval-convex surfaces in the patient's spine, holes 382A, 384A (Fig. 3) are precisely located and then formed in the bone structure using a measuring instrument centered in the evacuated natural intravertebral disc space. These holes are then tapped to form female threads therein. When the threads have been formed, the anchors 102, 104 are implanted in the respective tapped holes, thereby creating an imaginary platform of reference points located precisely with respect to the patient's spine. After the holes have been formed and the anchors 102, 104 implanted, a bone surface milling jig (not shown) is affixed to the anchors 102, 104 and the desired concave surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using one of a selection of predetermined milling head or bit sizes. Thereafter, the bone milling jig is removed and the concaval-convex elements 52, 54 identical in shape to the milled surfaces 112, 114 are inserted between the distracted milled vertebral bodies 12, 14. The distraction device is then moved. The concaval-convex structures are then attached by the same anchors 102, 104 to the bone, thus insuring a precise and stable mate between the bone surfaces and the convex surfaces 52, 54.

If necessary, a damaged implanted nucleus and/or gasket 24 can be removed and replaced. This can be accomplished by slitting the seal 110; removing the annular gasket 24 and damaged nucleus 22, and replacing them with new, undamaged elements. Thereafter, the seal 110 can be re-established by suturing or gluing closed the slit seal.

We claim,

1. A vertebral disc endoprosthesis, comprising a resilient body formed of materials varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion; and concaval-convex elements at least partly surrounding the resilient body between adjacent vertebral bodies for retaining the resilient body between adjacent vertebral bodies in a patient's spine, and wherein said concaval-convex elements each comprise generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the resilient body, each support further having a second leg extending generally perpendicularly to the first leg and adapted for affixation to adjacent bone structure.

2. A vertebral disc endoprosthesis according to Claim 1 wherein said resilient body comprises an annular gasket and a nuclear central portion.

3. A vertebral disc endoprosthesis according to Claim 1 further comprising cannulated screw means for attaching the concaval-convex element supports to adjacent bone structure.

4. A vertebral disc endoprosthesis according to Claim 3 wherein said cannulated screw means comprises a screw, and a screw anchor seatable within bone structure and adapted to threadably receive the screw.

5. A vertebral disc endoprosthesis according to Claim 1 further comprising a seal member attached to the concaval-convex elements and surrounding said resilient body.

6. A vertebral disc endoprosthesis according to Claim 5 wherein said seal member comprises a flexible shell material having a multiplicity of pores, the pores being from about 5 microns to about 60 microns in size.

7. A vertebral disc endoprosthesis according to Claim 6 further including sealing means applied to said flexible sheet material to render said flexible sheet material substantially impervious to the passage of any fluid.

8. A vertebral disc endoprosthesis according to Claim 5 wherein said concaval-convex elements and said seal member collectively surround said resilient body with a watertight seal.

9. A vertebral disc endoprosthesis according to Claim 2 wherein said annular gasket is relatively stiff and said nuclear central portion is relatively supple.

10. A vertebral disc endoprosthesis according to Claim 1 wherein said concaval-convex elements are formed of a biocompatible metal.

11. A vertebral disc endoprosthesis according to Claim 1 wherein said concaval-convex elements are formed of a metal containing titanium.

12. A vertebral disc endoprosthesis according to Claim 1 wherein said concaval-convex elements are formed of a metal containing chromium cobalt.

13. A vertebral disc endoprosthesis according to Claim 10 wherein said concaval-convex elements are each partly defined by exterior surfaces, and wherein the endoprosthesis further includes metal beading on at least part of the exterior concaval-convex element surfaces for encouraging bonding between bone and said exterior concaval-convex element surfaces.

14. A vertebral disc endoprosthesis according to Claim 1 wherein said concaval-convex elements are provided with roughened outer surfaces to encourage positive bonding of bone to said concaval-convex element surfaces.

15. A vertebral disc endoprosthesis according to Claim 1 wherein said concaval-convex elements are formed of a non-oncogenic material.

16. A vertebral endoprosthesis comprising an integral disc unit, said unit including a pair of confronting L-shaped supports having concaval-convex shapes in given legs, a resilient body interposed between the supports, and a flexible seal extending from one support to the other and sealing the resilient body within the supports inside a substantially watertight compartment.

17. A vertebral endoprosthesis according to Claim 16 further comprising a plurality of said integral disc units.

18. A vertebral disc endoprosthesis comprising a resilient nucleus, rigid concaval-convex elements at least partly surrounding the nucleus, an annular gasket ring surrounding the nucleus, and a seal member formed of flexible material and attached to the concaval-convex elements and surrounding the nucleus and the annular gasket ring.

19. A vertebral disc endoprosthesis according to Claim 18 wherein said concaval-convex elements each comprise generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the nucleus, each support further having a second leg extending generally perpendicularly to the first leg and adapted for affixation to adjacent bone structure.

20. A vertebral disc endoprosthesis, according to Claim 19 further including screw means adapted for connection to said legs and for affixation in a generally radial direction in adjacent generally cylindrical bone vertebrae.

21. A vertebral disc endoprosthesis according to Claim 18 further including means affixed to the concaval-convex elements for encouraging bone growth partially upon and bone bonding with said concaval-convex elements.

22. A vertebral disc endoprosthesis according to Claim 18 further including means for interconnecting one of said concaval-convex elements to a concaval-convex element of another vertebral disc endoprosthesis, thereby permitting the replacement of several natural vertebral discs.

23. A method of endoprosthetic discectomy surgery comprising the steps of receiving information about the size, shape and nature of a patient's damaged natural spinal vertebral bodies and discs from radiographs, CT and/or MRI scans or other imaging devices specifically determining the anterior-posterior and lateral dimensions of each involved vertebral body, the vertical height of the anterior aspect of each involved vertebral and/or proximate vertebral body, and the vertical height of the mid-portion of the involved and proximate normal intervertebral disc spaces, thereafter constructing one or more prosthetic vertebral body units and prosthetic

disc units in conformity with the received information, each prosthetic disc unit including confronting L-shaped concaval-convex elements and a resilient body interposed between the concaval-convex elements; and an endoprosthetic vertebral body interposed between and engaging the adjacent disc units; and thereafter implanting the completed and conformed construction in the patient's spine.

24. A method according to Claim 23 including the step of constructing a plurality of prosthetic disc units and further including the step of attaching the disc units to an endoprosthetic vertebral body prior to the step of supplying the assembly to the surgeon.

25. A method according to Claim 23 further including the steps of surgically milling spinal bone surfaces with concave surfaces to receive confronting convex surfaces of the concaval-convex elements, and installing at least one disc unit having concaval-convex elements with said convex surfaces in the patient's spine.

26. A method of surgery comprising the steps of removing a vertebral disc from a patient's spine, forming holes at precisely predetermined locations in bone structure adjacent the location of the removed disc, tapping the holes to form a female thread in each hole, and threadably implanting an anchor into each tapped hole, thereby creating an imaginary platform of reference points located precisely with respect to the patient's spine, forming concave surfaces in adjacent spinal bone, and inserting between the formed bone surfaces a vertebral disc endoprosthesis including confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with the adjacent formed concave spinal bone surface, the endoprosthesis further including a resilient body element interposed between the concaval-convex supports, and thereafter affixing the concaval-convex supports to the adjacent bone.

27. A method of surgery according to Claim 26 further including the step of temporarily locating a bone surface milling jig at the site of the removed vertebral disc by means of said anchors prior to implanting said disc endoprosthesis.

28. A method of surgery according to Claim 26 further including the steps of attaching a screw to each concaval-convex support and screwing said screw into an implanted anchor.

29. A method of surgery according to Claim 26 further comprising the steps of identifying a damaged resilient nucleus body element or annular gasket in an implanted endoprosthesis, removing said damaged nucleus body element or annular gasket from the endoprosthesis and inserting a new, undamaged nucleus body element or annular gasket into the endoprosthesis without removing the concaval-convex supports from the patient's spine.

30. A method of spinal surgery comprising the steps of forming mounting holes in one or more vertebral bodies of a patient's spine; utilizing said mounting holes to mount a bone mill on a patient's spine; milling confronting bone surfaces on and in the patient's spine to a predetermined surface shape; removing said mill; and thereafter mounting a vertebral disc endoprosthesis having a predetermined outer surface shape by means of the original mounting holes so that outer surfaces of the vertebral disc endoprosthesis mate precisely with the previously milled bone surfaces.

31. A vertebral disc endoprosthesis comprising a resilient nucleus, first and second rigid concaval-convex elements at least partly surrounding the nucleus, first and second legs formed, respectively, with the first and second rigid concaval-convex elements, first and second means for affixing the respective legs to vertebral bodies adjacent the concaval-convex elements and nucleus, and longitudinal ligament prosthesis means extending between the legs of the first and second concaval-convex elements to inhibit undesirable motion of the vertebral bodies relative to one another.

32. A vertebral disc endoprosthesis comprising a rounded, resilient nucleus body convex on all surfaces and concaval-convex elements, each concaval-convex element being of relatively constant cross-sectional thickness and having an outer convex surface for engaging adjacent bone structure which has been milled to mate with the concaval-convex element outer

convex surface, and a corresponding inner concave surface for engaging the rounded resilient body.

33. A vertebral disc endoprosthesis according to Claim 32 wherein said resilient nucleus body comprises a relatively resilient central body and a relatively stiff gasket surrounding a circumference of the central body, the resilient nucleus body snugly engaging the adjacent, mating concave surfaces of the concaval-convex elements.

34. A vertebral disc endoprosthesis according to Claim 33 wherein the concaval-convex elements do not engage one another.

35. A method of endoprosthetic discectomy surgery comprising the steps of receiving information about the size, shape and nature of a patient's involved and proximate normal natural spinal vertebral bodies and natural spinal vertebral discs from known imaging devices, thereafter constructing at least one vertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements at least partly surrounding the resilient disc body, removing at least the involved, natural spinal discs from the patient's spine and thereafter implanting the vertebral disc endoprosthesis in the patient's spine.

36. The vertebral disc endoprosthesis according to Claim 1 wherein each concaval-convex element is provided with a respective groove.

37. The vertebral disc endoprosthesis according to Claim 36 further comprising a seal member including beaded edges, the seal member attached to the concaval-convex elements and surrounding said resilient body.

38. The vertebral disc endoprosthesis according to Claim 37 further comprising retainer means for retaining the seal member against said grooves, the retainer means cooperating with the beaded edges and the grooves to form a watertight seal.

39. The vertebral disc endoprosthesis according to Claim 38 wherein the retainer means can be in one of the following forms: a biocompatible monofilament metal wire, a synthetic polymer band or a braided wire cable.

40. The vertebral disc endoprosthesis according to Claim 39 wherein the biocompatible monofilament metal wire is formed of stainless steel or titanium.

41. The vertebral disc endoprosthesis according to Claim 38 further comprising a crimping means for crimping the retainer means about the seal member.

42. The vertebral disc endoprosthesis according to Claim 1 wherein each support includes a groove about its circumference, the groove encircling the periphery of the first leg.

43. The vertebral endoprosthesis according to Claim 16 wherein each support includes a groove about its periphery and wherein the seal includes beaded edges.

44. The vertebral endoprosthesis according to Claim 43 further comprising retainer means for retaining the seal against said grooves, the retainer means cooperating with the beaded edges and the grooves to form a watertight seal.

45. The vertebral endoprosthesis according to Claim 44 wherein the retainer means can be in one of the following forms: a biocompatible monofilament metal wire, a synthetic polymer band or a braided wire cable.

46. The vertebral endoprosthesis according to Claim 45 wherein the biocompatible monofilament metal wire is formed of stainless steel or titanium.

47. The vertebral endoprosthesis according to Claim 44 further comprising a crimping means for crimping the retainer means about the seal.

48. The vertebral disc endoprosthesis according to Claim 18 wherein each element includes a respective groove and wherein the seal member includes beaded edges.

49. The vertebral disc endoprosthesis according to Claim 48 further comprising retainer means for retaining the seal member against said grooves, the retainer means cooperating with the beaded edges and the grooves to form a watertight seal.

50. The vertebral disc endoprosthesis according to Claim 49 wherein the retainer means can be in one of the following forms: a biocompatible monofilament metal wire, a synthetic polymer band or a braided wire cable.

51. The vertebral disc endoprosthesis according to claim 50 wherein the biocompatible monofilament metal wire is formed of stainless steel or titanium.

52. The vertebral disc endoprosthesis according to claim 49 further comprising a crimping means for crimping the retainer means about the seal member.

53. The vertebral disc endoprosthesis according to Claim 19 wherein each support includes a groove about its circumference.

54. The vertebral disc endoprosthesis according to claim 49 further comprising a crimping means for crimping the retainer means about the seal member.

Abstract of the Disclosure

The invention relates to a spinal disc endoprosthesis. The endoprosthesis has a resilient body formed of one or more materials which may vary in stiffness from a relatively stiff exterior annular gasket portion to a relatively supple central nucleus portion. Concave-convex elements at least partly surround that nucleus portion so as to retain the nucleus portion and gasket between adjacent vertebral bodies in a patient's spine. Assemblies of endoprosthetic discs, endoprosthetic vertebral bodies, and endoprosthetic longitudinal ligaments may be constructed. To implant this endoprosthesis assembly, information is obtained regarding the size, shape, and nature of a patient's damaged spine. Thereafter, one or more prosthetic vertebral bodies and disc units are constructed in conformity with that information. Finally, the completed and conformed vertebral body and disc assembly is implanted in the patient's spine.

FIG. 1

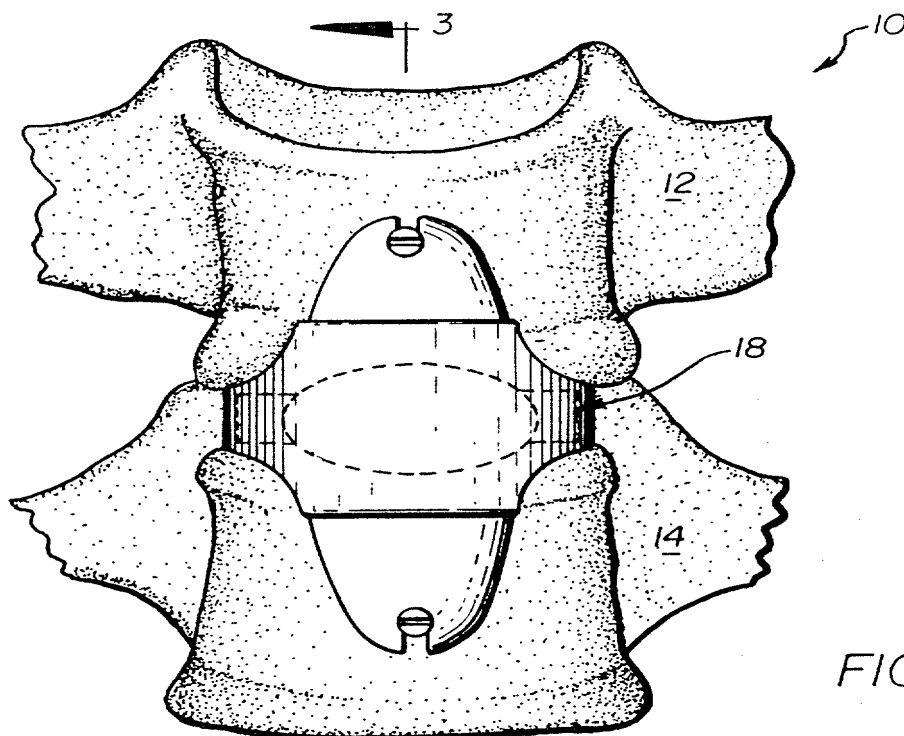


FIG. 2

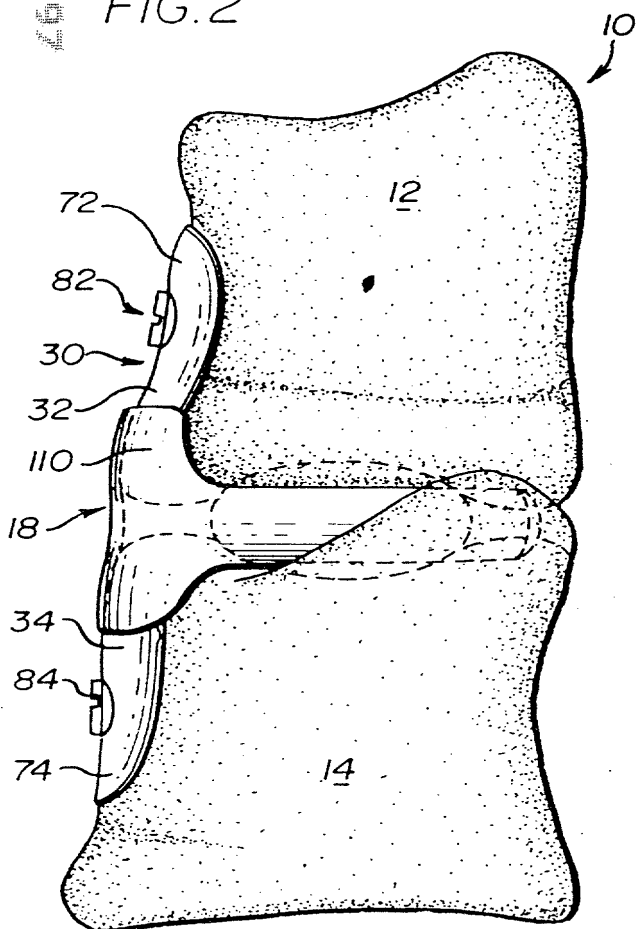
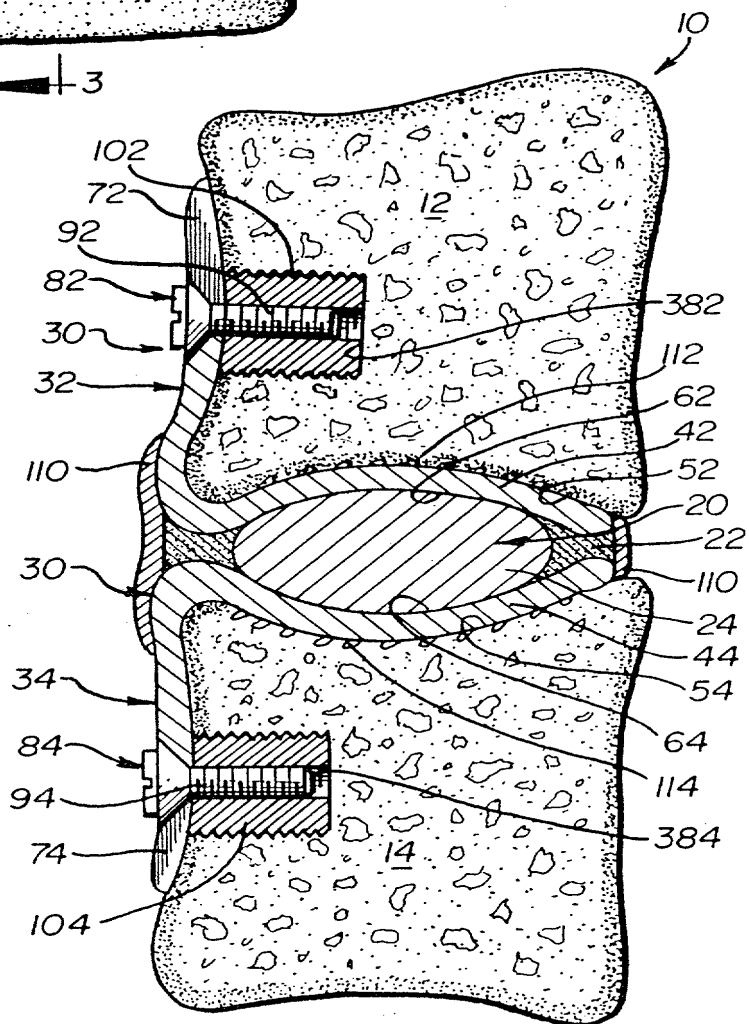


FIG. 3



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FIG. 4

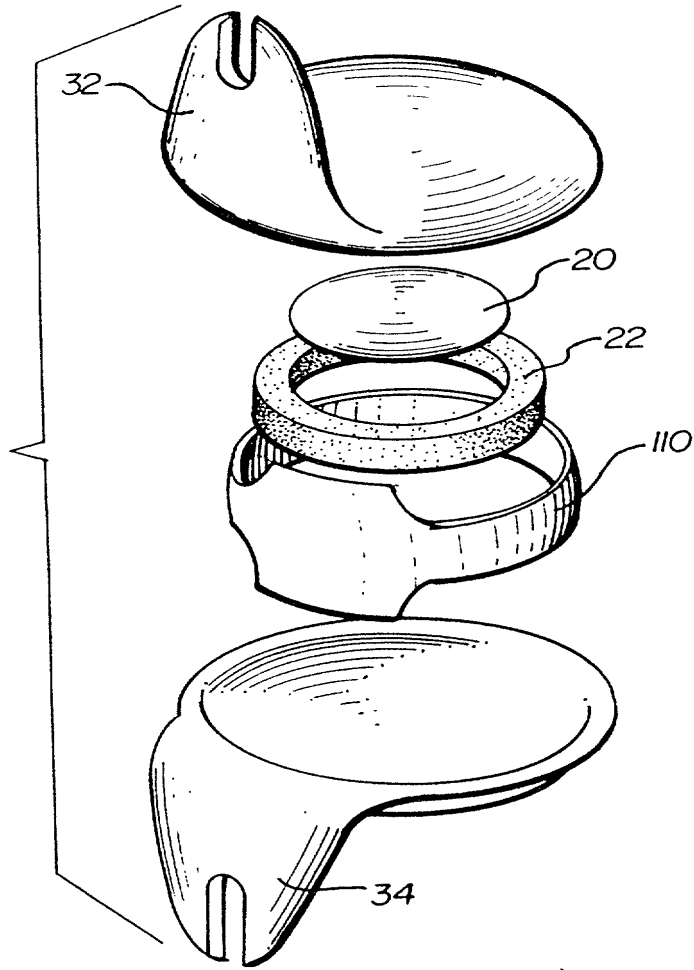


FIG. 5

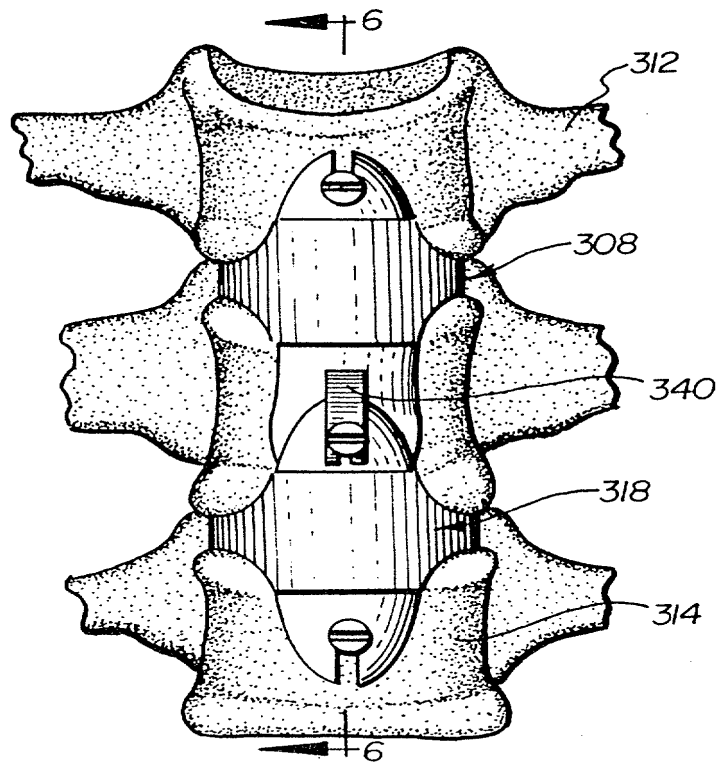


FIG. 7

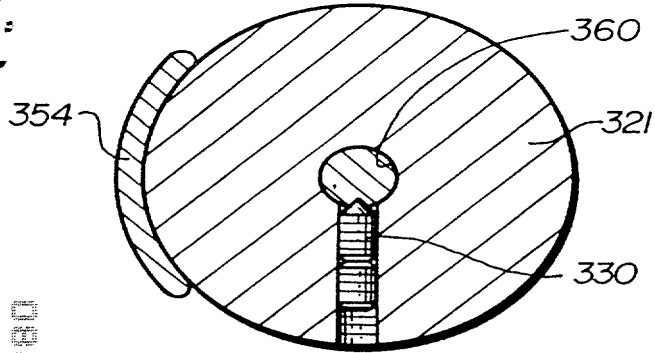


FIG. 6

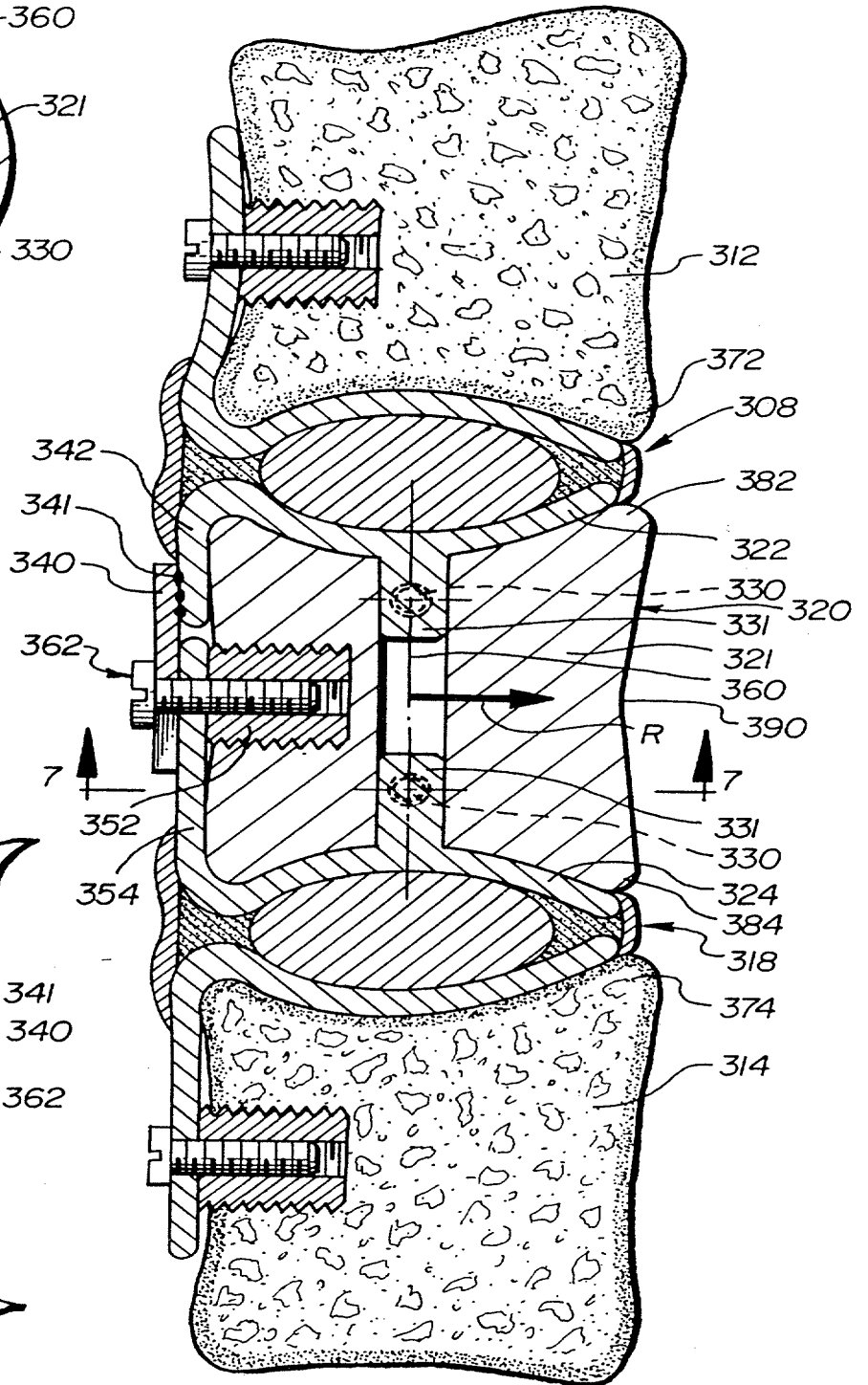


FIG. 8

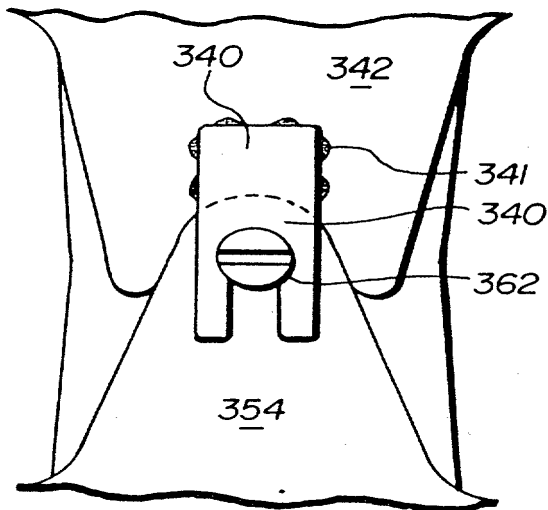


FIG. 9

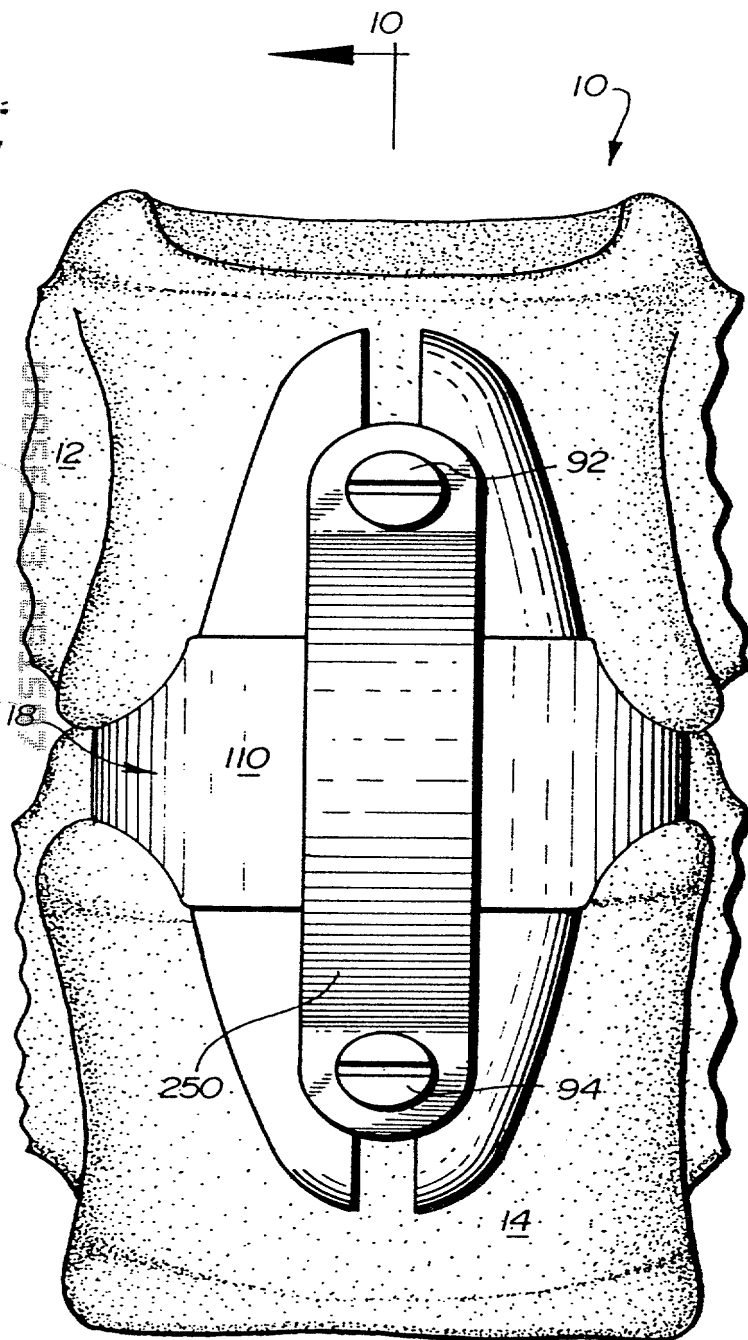
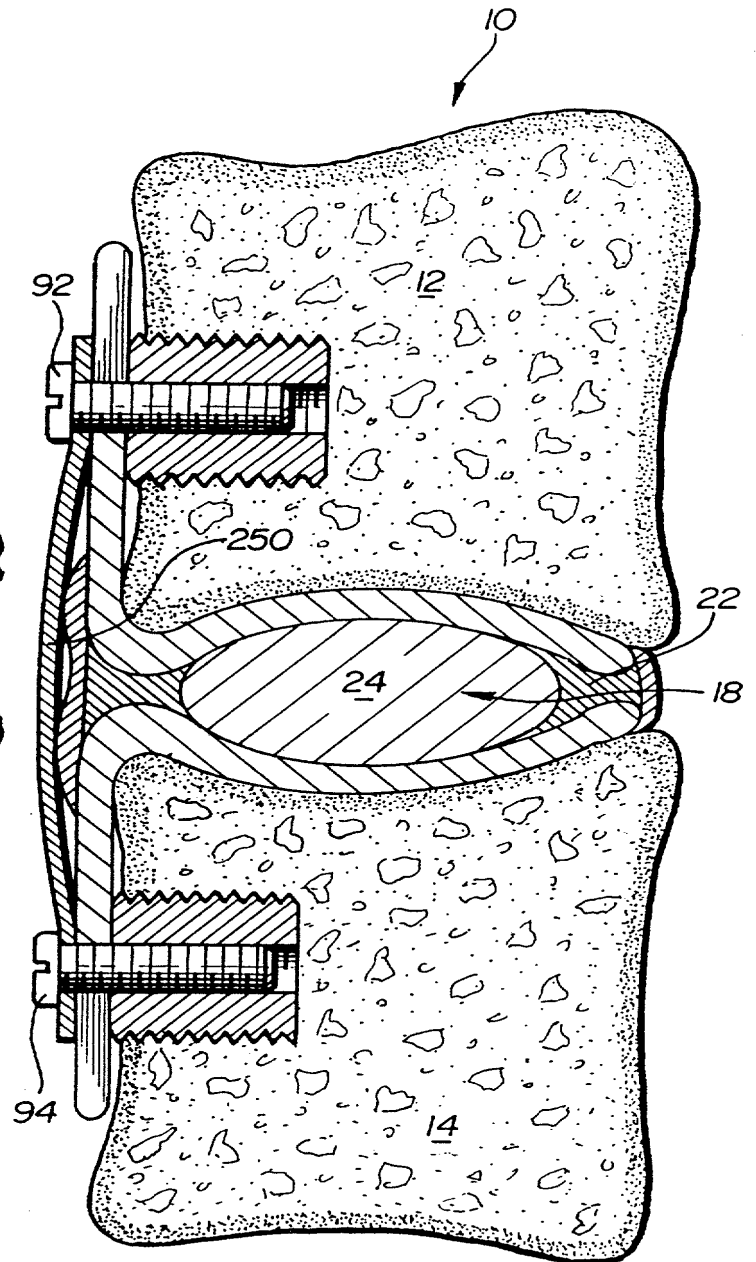


FIG. 10



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FIG. II

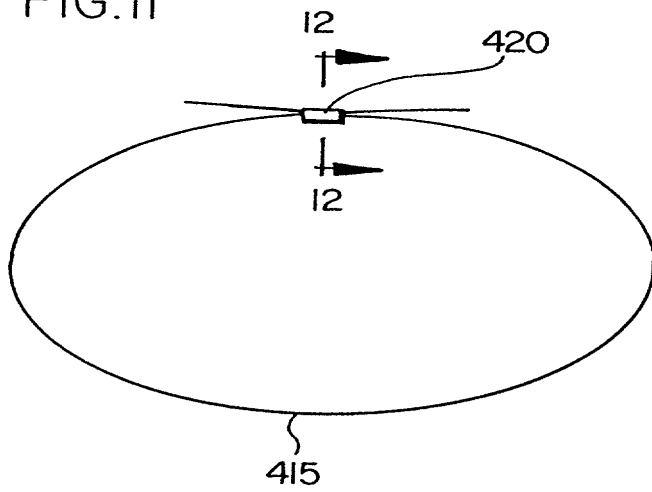


FIG. 12

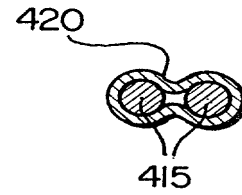


FIG. 13

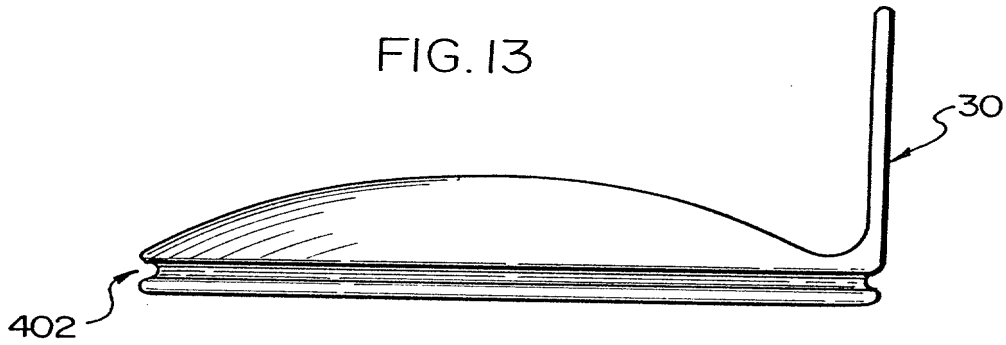
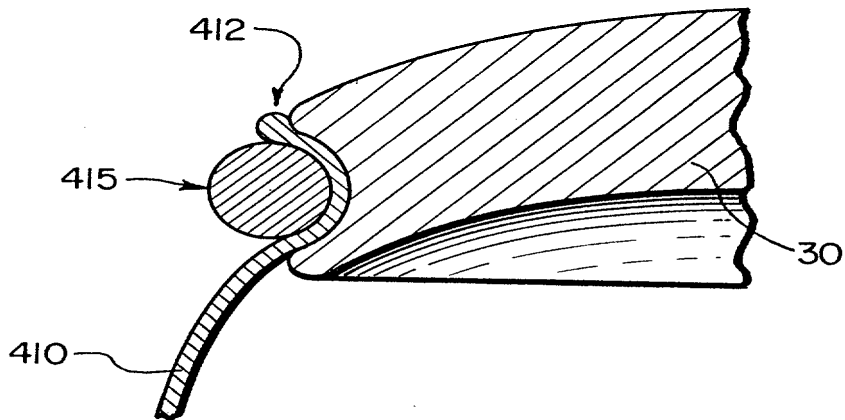


FIG. 14



Docket No.
P1113USA

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

HUMAN SPINAL DISC PROSTHESIS

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on July 22, 1996 as United States Application No. or PCT International Application Number 08/681,230 and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

_____	_____
(Application Serial No.)	(Filing Date)
_____	_____
(Application Serial No.)	(Filing Date)
_____	_____
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

08/339,490	11/14/94	PENDING
_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)
_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)
_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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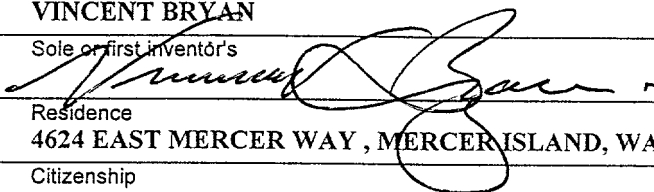
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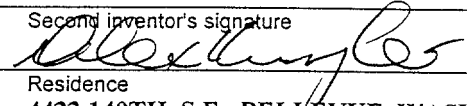
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